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EU's Artificial Intelligence (AI) Act

As part of the EU Digital Strategy, the European Commission has launched multiple legislative initiatives aimed to manage, regulate and support new technologies and digital evolutions in the EU. The AI Act is the first-ever legal framework for AI that regulates the development and use of AI systems to ensure their safety and trustworthiness.

PURPOSE

- Promote the **trustworthy and human-centric** application of AI – while supporting innovation within the EU.
- **Protect** fundamental rights, health, safety, democracy and the rule of law, and the environment from potential harmful effect.
- Promote the **development** of AI systems in a transparent and complaint manner.

APPROACH

- **Risk-based approach** categorizing AI systems by use case into categories, that drive compliance obligations for AI systems.
- **General purpose AI models (GPAI) posing systemic risk** will have to comply with additional obligations, given their wide-ranging application.

SCOPE

- **Any AI system affecting a person located in the EU**, regardless of where the system was developed or where the system is hosted, operated or monitored.
- The Act involves many stakeholders. It will mainly apply to **providers** (i.e. developers), **deployers** (i.e users in a professional context), **importers** and **distributers** of AI systems.

BROAD AND TECHNOLOGY-AGNOSTIC DEFINITION OF AI

An AI system is a machine-based system that is designed to operate with varying levels of **autonomy** and that may exhibit **adaptiveness** after deployment, and that, for explicit or implicit objectives, **infers**, from the input it receives, how to **generate outputs** such as predictions, content, recommendations, or decisions that can influence physical or virtual environments

TIMELINE

The AI Act enters into force on 1 August 2024 and applies **gradually,** starting on 2 February 2025 until full applicability by 2 August 2027. More detail is provided on the next page.
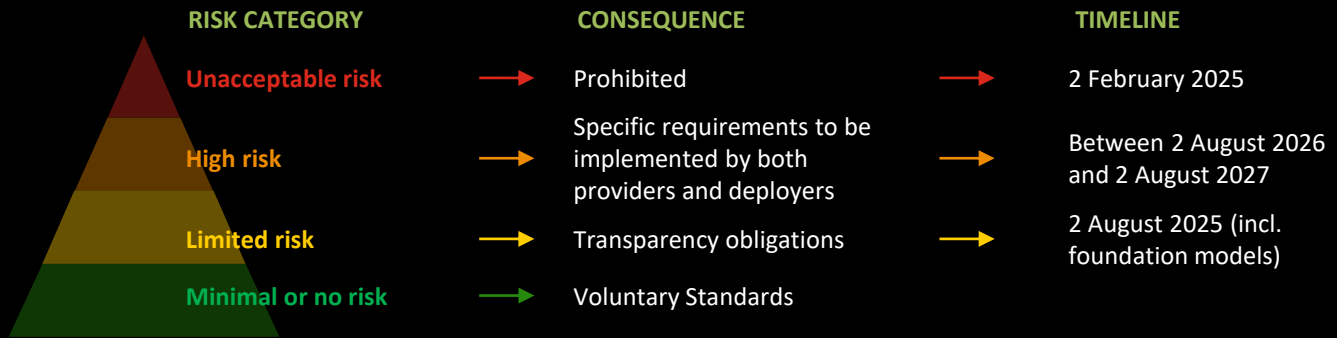
ENFORCEMENT

Member States will establish a **national supervisor** enforcing compliance. The **EU AI Office** coordinates across borders and monitors larger topics like GPAI. For some AI systems, a **conformity assessment** is required.

PENALTIES

Fines range from 35m€ / 7% global turnover (prohibited cases), 15m€ / 3% (other infringements), to 7,5m€ / 1,5% (reporting errors), as well as **non-monetary penalties** such as removal of the AI system from the market.

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RISK BASED APPROACH

Risk classification of AI systems depending on the perceived risk on the health, safety and fundamental rights.

RISK CATEGORY	CONSEQUENCE	TIMELINE
Unacceptable risk →	Prohibited	2 February 2025
High risk →	Specific requirements to be implemented by both providers and deployers	Between 2 August 2026 and 2 August 2027
Limited risk →	Transparency obligations	2 August 2025 (incl. foundation models)
Minimal or no risk →	Voluntary Standards	

HIGH RISK AI SYSTEMS (HRAIS)

The AI Act imposes requirements for High Risk AI Systems, such as technical documentation, risk management system, record keeping, transparency obligations, quality management system and post-market monitoring.

7 TRUSTWORTHY AI PRINCIPLES

1. Human agency and oversight
2. Technical robustness and safety
3. Privacy and data governance
4. Transparency
5. Diversity, non-discrimination and fairness
6. Environmental and social wellbeing
7. Accountability

GENERAL PURPOSE AI MODEL (GPAI)

For GPAI systems, the risk is measured by the power of the foundation model. Distinction between GPAI models and GPAI models with systemic risk due to their high impact capabilities for which additional obligations exist. Rules apply as of 2 August 2025.

STEPS TOWARDS COMPLIANCE

Early start of planning and preparations help organisations to embed AI Act compliance into their business processes, reducing costs and provide necessary safeguards for innovation.

Identification
Identify the 'AI systems', roles of stakeholders and perform an AI Act impact assessment

Classification
Perform a risk assessment and identify the risk category for the AI system

Declaration
Write a declaration of conformity (Annex V) for each high-risk AI system and affix the 'CE' marking

Monitoring
Establish monitoring and incident reporting to ensure that the model performs as intended

1   2   3   4   5   6   7

Compliance and AI Ethics
Ensure appropriate design and development aligned with the Trustworthy AI principles

Conformity assessment
For high-risk AI systems, conduct a conformity assessment

Market launch
Place the high-risk AI system on the market or into service

At Deloitte, we help clients to prepare for the AI Act. Besides the steps to take for regulatory compliance, we offer tailored steps in AI governance to boost your innovation and accelerate the scaling of your business.

Whether you need to achieve compliance of a specific AI system or install the right governance processes or guardrails for innovation, our multidisciplinary team is ready to help.

GET IN TOUCH
Geert Hallemeesch
Leader AI & Data
ghallemeesch@DELOITTE.com

Matthias Vierstraete, Attorney – Deloitte Legal - *Lawyers*
mvierstraete@DELOITTE.com